

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

ALICE ASHBURN, ADMX etc.,

Plaintiff,

Case No. 3:06 CV 2367

-vs-

MEMORANDUM OPINION
AND ORDER

GENERAL NUTRITION CENTERS, INC.,

Defendant.

KATZ, J.

On August 23, 2007 an evidentiary hearing was conducted by the Court at which Plaintiff elicited the testimony of Donald H. Marks, MD, Ph.D and Defendant, GNC, elicited the testimony of Richard B. Kreider, Ph.D. The parties filed pre-hearing briefs on August 1, 2007 and have subsequently filed briefs in support of their respective motions to exclude expert testimony of the two witnesses noted above. After a review of the transcript of that hearing, and of all memoranda filed by the parties in connection with the issues raised by the competing motions, the Court will grant Defendant's motion to exclude Dr. Marks and deny Plaintiff's motion to exclude Defendant's expert Richard B. Kreider, Ph.D.

DAUBERT STANDARD

The legal standard to be used in *Daubert* challenges was set forth by Judge Bechtle in his memorandum opinion issued on February 1, 2001:

Federal Rule of Evidence 702 obligates judges to ensure that any scientific testimony or evidence admitted is relevant and reliable. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999) (quoting *Daubert*, 509 U.S. at 589). The party offering the expert has the burden of proving admissibility. *Daubert*, 509 U.S. at 592 n.10. The subject of an expert's testimony must be grounded in the methods and procedures of science and based on more than subjective belief or

speculation. *Id.* at 589-590. Further, Rule 702 requires that expert testimony assist the trier of fact, i.e., it must “fit” the issues in the case by having a “valid scientific connection to the pertinent inquiry.” *Id.* at 591-92.

In determining “whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact,” the court must assess whether the methodology underlying the testimony is scientifically valid and whether it can properly be applied to the facts in issue. *Id.* at 592-93. Furthermore, the court must examine the expert’s conclusions in order to determine whether they can reliably follow from the facts known to the expert and the methodology used. *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 153 (3d Cir. 1999).

In *Daubert*, the Court identified several factors to assist courts in evaluating whether a scientific theory or methodology constitutes reliable scientific knowledge. These include: whether the theory or technique can be or has been tested; whether the theory has been subjected to peer review and publication; whether a technique has a known or potential rate of error and whether there are standards controlling the technique’s operation; and whether the theory or method has general acceptance in the scientific community. *Daubert*, 509 U.S. at 593-94. These factors “are simply useful signposts, not dispositive hurdles that a party must overcome in order to have expert testimony admitted.” *Heller*, 167 F.3d at 152.

In addition, a court should “exclude proffered expert testimony if the subject of the testimony lies outside the witness’s area of expertise.” 4 Weinstein’s Fed. Evid. § 702.06[1], at 702-52 (2000). In other words, a party cannot qualify as an expert generally by showing that the expert has specialized knowledge or training which would qualify him or her to opine on some other issue. *Redman v. John D. Brush & Co.*, 111 F.3d 1174, 1179 (4th Cir. 1997); *Barrett v. Atl. Richfield Co.*, 95 F.3d 375, 382b (5th Cir. 1996).

Moreover, testimony of an expert that constitutes mere personal belief as to the weight of the evidence invades the province of the jury. *McGowan v. Cooper Indus., Inc.*, 863 F.2d 1266, 1273 (6th Cir. 1987); *STX, Inc. v. Brine, Inc.*, 37 F. Supp. 2d 740, 768 (D.Md. 1999) (quotation omitted), *aff’d*, No. 99-1540, 2000 WL 564010 (Fed. Cir. May 8, 2000); *Sec. & Exch. Comm’n v. Lipson*, 46 F. Supp. 2d 758, 763 (N.D. Ill. 1998).

Lastly, the court “should also be mindful of other applicable rules.” *Daubert*, 509 U.S. at 595. Federal Rule of Evidence 703 “provides that expert opinions based on otherwise inadmissible hearsay are to be admitted only if the facts and data are ‘of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject.’” *Id.* (quoting Fed. R. Evid. 703). Under Rule 703, “[i]f the underlying data are so lacking in probative force and reliability that no reasonable expert could base an opinion on them, an opinion which rests entirely upon them must be excluded.” *In re Paoli RR. Yard PCB Litig.*, 35 F.3d [717,] 748 (quoting *In re “Agent Orange” Prod. Liab. Litig.*, 611 F. Supp. 1223, 1245 (E.D.N.Y. 1985).

In re: "Diet Drugs (Phenermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig., No. MDL 1203, 2001 WL 454586, at *5-6 (E.D. Pa. Feb. 1, 2001) (footnotes omitted). The district court is not required to hold a hearing to address a *Daubert* issue. *See Greenwell v. Boatwright*, 184 F.3d 492, 498 (6th Cir. 1999).

With this framework in place, the Court now turns to address each of the proposed witnesses *in seriatim*.

DONALD H. MARKS, M.D., PH.D.

Plaintiff has proposed Dr. Marks as an expert witness on her behalf. Dr. Marks is a well established physician who has been in practice for over 25 years, is a diplomat of the American Board of International Medicine, a fellow of the American College of Physicians, and a member of the Academy of Pharmaceutical Physicians. (His CV contains multiple examples of his expertise within his field). He currently maintains an active clinical practice treating roughly 400 patients, approximately 45% of whom are African-American. He has worked for pharmaceutical companies in creating protocols for epidemiologic studies and analyzing adverse effects to determine possible causal relationships. (See page 2 of Plaintiff's Memorandum, Doc. No. 74). It has been pointed out to this Court that Dr. Marks has never been rejected as a result of a *Daubert* hearing.

At the *Daubert* hearing, Dr. Marks discussed three separate triggers of dehydration, including fluid shift or "third spacing of fluids", the primary focus of the instant case. As noted by Plaintiff's counsel:

creatine, a small molecule that can transverse the capillaries, is an osmotically active substance that sucks fluid along with it as it leaves the vessels and enters the muscle cells. (TR 38) This intravascular loss of fluid produces a transient hyper-

concentration of the blood remaining in the vessels, making sickling of the red blood cells possible, especially when the patient is exercising.

Ultimately, Dr. Marks indicated that “capillaries then become clogged with the sickled red blood cells and the tissues ordinarily supplied oxygen by the blood infarct.” (TR 29-33). Unfortunately, as described by Dr. Marks, this is a “one-way trip, once the hemoglobin precipitates out you cannot really reverse it.” (TR 33).

Plaintiff points to the autopsy report of the Wood County Coroner’s Office, but does not follow that with a recognition that the writer of the report later recanted that creatine can cause dehydration by drawing water from the vessels into other body parts, thus transforming a sickle cell trait into a hemolytic crises. Further, there is proof lacking as to whether, when and how much Mr. Richardson consumed of the creatine supplement alleged to be the offending agent causing the onset of what developed into the cause of his death; there is no evidence suggesting that Mr. Richardson ingested the fluid at any time near the date of his death or, if so, in what amounts. All that was found was a bottle partially emptied of the supplement. That can hardly permit a leap to the assertion by Plaintiff that, based on expert medical testimony, Mr. Richardson’s ingestion of creatine was a substantial factor in causing his death.

While Dr. Marks’ opinions appear to be grounded in his view of biological plausibility, there has been no establishment of the prerequisite of general causation. General causation is “established by demonstrating that exposure to the substance in question causes or is capable of causing the trauma or disease; for example, smoking cigarettes causes lung cancer.” (Federal Reference Manual of Scientific Evidence (2nd Ed.) p. 581). Further, upon cross examination Dr. Marks was asked: “Prior to being contacted by Mr. Murray, had you done any study concerning the use of creatine?” To this question he answered: “No.” (TR 49), and at page 158 of the

transcript he was asked: “Would you agree with me that your contention that there was some causal link between creatine and a harmful fluid shift in Aaron Richardson is based on a differential diagnosis?” To that he answered: “Well, yes, it is. We went through the differential diagnosis of Mr. Richardson’s case. We arrived at stating that he died from acute sickle crisis caused by an underlying sickle trait which was precipitated by only one of two things, hypoxia, which didn’t exist, or anemia, I mean dehydration. And then we went through the causes of dehydration, which is fluid loss, inadequate intake or fluid shifts. And we eliminated fluid loss and inadequate fluid intake and arrived at fluid shift. And so now I think that what we are trying to discuss is whether the fluid shift *could* have been caused by the creatine.” (Emphasis added).

Clearly, Dr. Marks had not previously considered the issue on which he is asked to opine, and only did so after he was contacted by counsel for Plaintiff in this case. Thus, his opinions were developed solely for this case, have not been tested in the market place of ideas by having been peer reviewed and does not believe testing his hypothesis on individuals with sickle cell trait would be ethical because it would subject them to a risk of harm, including death. Where there is an absence of peer review and testing, the *Daubert* standards which have been developed by the Courts cannot in the instant case be satisfied.

Buttressing this conclusion is the position of Dr. Stephen Cantrill, a witness in related litigation involving Bowling Green State University and the within Plaintiff. Dr. Cantrill had originally indicated that creatine has the potential effect of dehydration. In a letter faxed August 22, 2007 and set forth as Exhibit K to Defendant’s post-hearing brief herein, Dr. Cantrill advised as follows:

* * * I further investigated the possibility of creatine (as a nutritional supplement) contributing to either dehydration or heatstroke. As you know, I do not hold

myself out to be an expert in the fields of nutrition or toxicology, but I have been unable to find any scientific evidence in the medical literature that would support any contribution by creatine in the development of either dehydration or heat stroke.

With respect to the issue of creating an opinion solely for the subject litigation, the Sixth Circuit case of *Johnson v. Manitowoc Boom Trucks, Inc.*, 484 F.3d 426 (6th Cir. 2007) is instructive. In that opinion, the Magistrate Judge at the district court level is quoted to have found, “. . . the expert’s opinions were conceived, executed and invented solely in the context of this litigation.” The Sixth Circuit addressed that issue and articulated the following:

If it is clear that a proposed expert’s testimony flows naturally from his own current or prior research (or field work), then it may be appropriate for a trial judge to apply the *Daubert* factors in a somewhat more lenient fashion.

Id. At 435 (emphasis added).

This matter clearly comes under Fed. R. Evid. 702, which mandates that expert testimony must be based on sufficient underlying facts or data. The term “data” is intended to encompass the reliable opinions of other experts. The advisory note to Rule 702 is instructive:

Rule 702 sets forth the overarching requirement of reliability, and an analysis of the sufficiency of the expert’s basis cannot be divorced from the ultimate reliability of the expert’s opinion. . . . However, the question whether the expert is relying on *sufficient* basis of information or not is governed by the requirements of Rule 702.

(Emphasis in original).

This is not a case where Dr. Marks has had a long history of considering the influence of creatine or creatine supplement on African-Americans with the sickle trait. It has been considered by him only recently and in connection with the subject case. There has been absolutely no peer review of his “research or thesis” or of his conclusory opinion. Neither has there been any testing to provide the necessary requisite reliability of those opinions.

Based on the inability of the Court to find that Dr. Marks, while obviously an experienced and outstanding physician, has offered an opinion or opinions which can pass muster under the stringent prerequisites of Rule 702 or the *Daubert* standard, the Court will grant Defendant's motion to exclude his testimony.

RICHARD B. KREITER, PH.D

Dr. Kreiter is presented to the Court as qualified to opine on general causation issues related to creatine. That is the limit of the area in which he is offered as an expert. As reflected in the testimony at the *Daubert* hearing and by his CV, Dr. Kreiter has a masters degree and a Ph.D in exercise physiology, in excess of 20 years experience in the nutritional supplement field and has conducted multiple studies on creatine as reflected in many articles on the supplement. Those articles have been published, subjected to peer review, and apparently accepted within the scientific community. The primary thrust of Plaintiff's attempt to discredit Dr. Kreiter arises out of the monies he has garnered from nutritional supplement purveyors, thus leading to the allegations that he is biased towards the nutritional supplement industry. Defendant points out that of the approximate \$10 million in grants Dr. Kreiter has received, only 14% was funded by manufacturers or distributors of nutritional supplements. That issue impacts the weight a trier of fact attributes to his testimony, not the prerequisites to qualifying as an expert on the issue at hand.

The testimony reflects that Dr. Kreiter's background includes conducting an analyzing extensive research on the subject, and thus he is offered as qualified to render an opinion regarding Dr. Marks differential diagnosis methodology and his theory of intra-cellular fluid change. The Defendant presents Dr. Kreiter because he has taught classes in the area and possesses both the education and scientific background necessary to competently opine on general

causation. It is asserted that research on the physiological effects of creatine is frequently conducted in laboratories and at universities by exercise physiologists.

It appears to this Court that Dr. Kreiter's testimony is founded on testing, peer reviewed research and writing and his more than 20 years of experience. He has conducted his own research and analyzed other research on intracellular dehydration, teaches classes in the area and has multiple articles on creatine as well as other nutritional supplements which have been published, peer reviewed and apparently accepted in the scientific community. In summary, it appears to this Court that Dr. Kreiter is qualified as an expert within the field and should be permitted to opine on the general causation issues at issue in this case. Although he is not a medical doctor, the foregoing would seem appropriate, while recognizing that he cannot offer an opinion on specific causation of the death of Aaron M. Richardson.

Plaintiff's motion to strike Dr. Kreiter as an expert qualified to testify as outlined above will be denied.

SUMMARY

Based on the foregoing the Court grants Defendant's motion to exclude the testimony of Dr. Marks and denies Plaintiff's motion to exclude the testimony of Dr. Kreiter.

IT IS SO ORDERED.

s/ David A. Katz
DAVID A. KATZ
U. S. DISTRICT JUDGE